

**In the Claims**

Please amend the claims as follows.

1     Claims 1-4 (canceled).

1     5.     (Currently amended) A method for forming a pathway from a sub-intimal space  
2     of a blood vessel into a true lumen of the blood vessel, comprising:  
3           positioning a catheter system within the sub-intimal space at a position proximate  
4     to a target entry site into the ~~vessel~~ true lumen, the catheter system including at least one  
5     lumen in communication with at least one port in a distal region of the catheter system,  
6     the catheter system further including an internal incising element that is translatable  
7     across a portion of the port;  
8           determining a radial position of the true lumen with respect to the port at the  
9     target entry site from a position in the sub-intimal plane using an imaging device of the  
10    catheter system; and  
11           forming an incision in tissue separating the sub-intimal space from the true lumen  
12    using the internal incising element, the incision having separate and distinct end points  
13    and forming a pathway between the sub-intimal space and the true lumen, wherein the  
14    tissue remains external to the port subsequent to forming the incision.

1     6.     (Previously added)     The method of claim 5, wherein the imaging device is a  
2     rotational imaging device.

1     7.     (Withdrawn)     The method of claim 5, wherein the imaging device is an ultrasonic  
2     device.

1     8.     (Withdrawn)     The method of claim 5, wherein the imaging device is an optical  
2     coherence tomography (OCT) device.

1 9. (Withdrawn) The method of claim 5, wherein the incising element is integral to  
2 the imaging device.

1 10. (Withdrawn) The method of claim 5, wherein the incising element is separate  
2 from and arranged concentrically outside the imaging device.

1 11. (Previously added) The method of claim 5, wherein determining the radial  
2 position includes use of an imaging device that is a fixed integral part of a body of the  
3 catheter system.

1 12. (Withdrawn) The method of claim 5, wherein determining the radial position  
2 includes use of a fluoroscopic marker on the catheter system.

1 13. (Withdrawn) The method of claim 12, wherein the fluoroscopic marker is  
2 located on a body of the catheter system.

1 14. (Withdrawn) The method of claim 12, wherein the fluoroscopic marker is  
2 located on one or more working elements of the catheter system.

1 15. (Previously added) The method of claim 5, further comprising evacuating fluid  
2 from the sub-intimal space and securing the tissue separating the sub-intimal space from  
3 the true lumen at the port by applying vacuum to the catheter lumen.

1 16. (Previously added) The method of claim 15, further comprising invaginating  
2 the tissue separating the sub-intimal space from the true lumen into the port and into a  
3 distal interior region of the catheter system upon application of the vacuum.

1 17. (Previously added) The method of claim 5, further comprising advancing a  
2 working element into the true lumen through the incision.

1 18. (Previously added) The method of claim 17, wherein the working element  
2 includes at least one of a guide wire and a cannula.

1 19. (Currently amended) A method for forming a pathway from a sub-intimal space  
2 of a blood vessel into a true lumen of the blood vessel, comprising:

3 positioning a catheter system within the sub-intimal space at a position proximate  
4 to a target entry site into the vessel true lumen, the catheter system including at least one  
5 lumen in communication with at least one port in a distal region of the catheter system,  
6 the catheter system further including an internal incising element that is translatable  
7 across a portion of the port; and

8 forming an incision in tissue separating the sub-intimal space from the true lumen  
9 using the internal incising element, the incision having separate and distinct end points  
10 and forming a pathway between the sub-intimal space and the true lumen, wherein the  
11 tissue remains external to the port subsequent to forming the incision.

1 20. (Currently amended) A method for forming a pathway from a sub-intimal space  
2 of a blood vessel into a true lumen of the blood vessel, comprising:

3 positioning a catheter system within the sub-intimal space at a position proximate  
4 to a target entry site into the vessel true lumen, the catheter system including at least one  
5 lumen in communication with at least one port in a distal region of the catheter system,  
6 the catheter system further including an internal excising element that is translatable  
7 across a portion of the port;

8 determining a radial position of the true lumen with respect to the port at the  
9 target entry site from a position in the sub-intimal plane using an imaging device of the  
10 catheter system;

11 advancing the internal excising element along a portion of the port; and

12 excising an area of tissue separating the sub-intimal space from the true lumen  
13 using the internal excising element, the excised area of tissue generating a pathway from  
14 the sub-intimal space to the true lumen.

1 21. (Currently amended) A method for forming a pathway from a sub-intimal space  
2 of a blood vessel into a true lumen of the blood vessel, comprising:

3 positioning a catheter system within the sub-intimal space at a position proximate  
4 to a target entry site into the ~~vessel~~ true lumen, the catheter system including at least one  
5 lumen in communication with at least one port in a distal region of the catheter system,  
6 the catheter system further including an internal excising element that is translatable  
7 across a portion of the port;

8 advancing the internal excising element along a portion of the port; and

9 excising an area of tissue separating the sub-intimal space from the true lumen  
10 using the internal excising element, the excised area of tissue generating a pathway from  
11 the sub-intimal space to the true lumen.

1 22. (Currently amended) A method for establishing a pathway through a chronic  
2 total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of  
3 the blood vessel which is proximal to the occlusion to a second region of the true lumen  
4 of the blood vessel distal to the occlusion via an extra-luminal pathway within the vessel,  
5 comprising:

6 forming a track longitudinally from the first region of the true lumen through the  
7 occlusion and into a sub-intimal space distal to the occlusion;

8 positioning a catheter system within the sub-intimal space using the track, the  
9 catheter system including at least one lumen in communication with at least one port in a  
10 distal region of the catheter system, the catheter system further including an internal  
11 incising element that is translatable across a portion of the port;

12 determining a radial position of the true lumen with respect to the port using an  
13 imaging device of the catheter system; and

14 forming an incision in tissue separating the sub-intimal space from the true lumen  
15 using the internal incising element, the incision having separate and distinct end points  
16 and forming a pathway between the sub-intimal space and the true lumen, wherein the  
17 tissue remains external to the port subsequent to forming the incision.

1 23. (Previously added) A method for establishing a pathway through a chronic  
2 total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of  
3 the blood vessel which is proximal to the occlusion to a second region of the true lumen  
4 distal to the occlusion via an extra-luminal pathway within the vessel, comprising:  
5 forming a track longitudinally from the first region of the true lumen through the  
6 occlusion and into a sub-intimal space distal to the occlusion;  
7 positioning a catheter system within the sub-intimal space using the track, the  
8 catheter system including at least one lumen in communication with at least one port in a  
9 distal region of the catheter system;  
10 determining a radial position of the true lumen with respect to the port using an  
11 imaging device of the catheter system;  
12 applying a vacuum through the catheter lumen and the port, evacuating fluid from  
13 the sub-intimal space and bringing the sub-intimal tissue into intimate contact with the  
14 port; and  
15 advancing a working element through the port and through the tissue separating  
16 the sub-intimal space and the second region of the true lumen and generating a pathway  
17 from the sub-intimal space to the second region of the true lumen.

1 Claims 24-42 (canceled).